UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action**
	)	**No. 01-1539 (GK)**
TOMMY G. THOMPSON, Secretary, Department of Health and Human Services, et al.,	)	
	)	
Defendants,	)	
	)	

MEMORANDUM OPINION

Plaintiffs are individuals and companies with a direct financial interest in dietary supplements containing vitamins C and E ("antioxidant vitamins") as well as a non-profit therapeutic health organization composed of physician members who sell dietary supplements containing antioxidant vitamins.[1] They bring this action against Defendants Tommy F. Thompson, Secretary, United States Department of Health and Human Services ("HHS"), in his official capacity; HHS; Bernard A. Schwetz, Acting Principal Deputy Commissioner of the Food and Drug Administration ("FDA"), in his official capacity; Joseph A. Levitt, Director of the Center for Food and Safety and Applied Nutrition of the FDA, in his official

[1] Plaintiffs are Julian M. Whitaker, M.D., Pure Encapsulations, Inc., Wellness Lifestyles, Inc. d/b/a American Longevity, Durk Pearson and Sandy Shaw, and the American Association for Health Freedom (previously known as the American Preventive Medical Association).

capacity; Christine J. Lewis, Ph.D., Director of the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition of the FDA, in her official capacity; and the United States of America.

Plaintiffs challenge the FDA decision prohibiting dietary supplements' labels from including the health claim that "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers" ("Antioxidant Vitamin Claim" or "Claim"). Plaintiffs contend that the FDA's decision violates the First Amendment, the Fifth Amendment, the Defendants' oaths of office to uphold the Constitution, 5 U.S.C. § 3331, the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 343(r)(1)(B), and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. Plaintiffs seek a preliminary injunction enjoining the FDA from taking any action which would prevent the use of the desired antioxidant vitamin health claim as proffered or with reasonable disclaimers.

This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction [#4]. Upon consideration of the Motion, Opposition, Reply, the Excerpts of Record, and the entire record herein, for the reasons discussed below, Plaintiffs' Motion for a Preliminary Injunction is **granted.**

I. Background

A. Statutory Framework

Prior to November 8, 1990, the FDCA, 21 U.S.C. § 301 et seq., provided that dietary supplements--including the supplements containing the antioxidant vitamins at issue in this case--would be regulated as a "food," unless their intended use was as a "drug."[2] If a food or dietary supplement label[3] contained a health claim,[4] the FDA deemed the product to be a drug, and it then became subject to the FDA's rigorous drug approval and drug labeling requirements. See 21 U.S.C. §§ 321(g)(1)(B) and 355.

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[2] A "dietary supplement" is defined, in part, as a "product . . . intended to supplement the diet" which contains a vitamin, mineral or other enumerated substance. 21 U.S.C. § 321(ff). "Food" is defined, in part, as "articles used for food or drink." 21 U.S.C. § 321(f)(1). "Drugs" are defined, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

[3] A "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). For purposes of this Opinion, there is no need to distinguish between "labels" and "labeling," the latter of which is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

[4] "Health claims" are statements that describe a relationship between a nutrient, such as calcium, and a disease or health-related condition, such as osteoporosis. See 21 U.S.C. § 343(r)(1)(B).

On November 2, 1990, Congress amended the FDCA by enacting the Nutrition Labeling and Education Act ("NLEA" or "Act").[5] The NLEA liberalized the FDCA, creating a "safe harbor" from "drug" designation for dietary supplements and foods that make health claims. See 21 U.S.C. § 343(r)(1)(B). Under the Act, so long as a health claim for dietary supplements is made in accordance with 21 U.S.C. § 343(r)(5)(D) as well as other sections of the statute, the claim is not subject to the FDCA's far more extensive and demanding approval and labeling requirements for drugs. See 21 U.S.C. § 321(g)(1)(B).

The NLEA also established the procedure for FDA authorization and evaluation of health claims for foods and dietary supplements. The Act directed that health claims for conventional foods shall be approved

> only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 U.S.C. § 343(r)(3)(B)(i). However, a different authorization procedure was provided for health claims for dietary supplements. Instead of mandating a particular standard as it did for

[5] Pub. L. No. 101-535, 104 Stat. 2353, codified as amended at 21 U.S.C. §§ 301, 321, 337, 343, 371 (1990).

conventional foods in § 343(r)(3)(B)(i), Congress broadly delegated to the FDA the task of developing an appropriate procedure for evaluating and authorizing health claims for dietary supplements. The relevant section merely provides that health claims

> made with respect to a dietary supplement . . . shall be subject to a procedure and standard, respecting the validity of such a claim, established by regulation of the Secretary.

21 U.S.C. § 343(r)(5)(D). The FDA responded to section 343(r)(5)(D) by promulgating 21 C.F.R. § 101.14, which adopted the same standard for authorizing dietary supplement health claims as the NLEA prescribed for authorizing food health claims--significant scientific agreement. The Act also specifically directed the FDA to consider whether health claims could be authorized for a number of specified nutrient-disease relationships, including the antioxidant vitamin/cancer relationship. See 21 U.S.C. § 343(r)(5)(D); NLEA, Pub. L. 101-535, § 3(b)(1)(A)(x).

B. Procedural History

After a lengthy rule-making procedure under the APA, the FDA adopted a final rule prohibiting claims associating antioxidant vitamins with cancer on January 6, 1993. See 58 Fed. Reg. 2622 (Jan. 6, 1993); Excerpts of the Record ("E.R.") Tab 5. The FDA found significant scientific agreement that there was evidence supporting the relationship between a decreased risk of several

types of cancer and "diets rich in fruits and vegetables, which are generally low in fat and high in vitamin A (as beta-carotene), vitamin C, and dietary fiber." 58 Fed. Reg. at 2622 (emphasis added). However, the FDA did not find that such evidence was "sufficient to attribute the reduction in risk specifically to...vitamin C, or vitamin E, alone or in combination, or to other components of these diets." 58 Fed. Reg. at 2622. Nine months later, the FDA reiterated its refusal to authorize health claims associating antioxidant vitamins with cancer. See 58 Fed. Reg. 53296 (Oct. 14, 1993); E.R. Tab 6.

1. The Pearson Plaintiffs

On November 16, 1995, Plaintiffs Durk Pearson, Sandy Shaw, and the American Preventive Medical Association ("Pearson Plaintiffs") brought suit arguing that the FDA had violated the First Amendment, the APA, and other laws through its unlawful suppression of four health claims, including the Antioxidant Vitamin Claim,[6] and requesting that the court invalidate the FDA's decision. On January 12, 1998, this Court upheld the FDA's decision and granted summary judgment in its favor. See Pearson v. Shalala, 14 F. Supp. 2d 10 (D.D.C. 1998).

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[6]The additional health claims challenged by the plaintiffs (dietary fiber/cancer, omega-3 fatty acids/coronary heart disease, and folic acid/neural tube defects) are not at issue in this action.

On January 15, 1999, the Court of Appeals for the District of Columbia Circuit reversed and remanded the case with instructions to remand it in turn to the FDA for reconsideration of the prohibited health claims, including Plaintiffs' Antioxidant Vitamin Claim, in light of its discussion of the relevant legal issues. See Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) ("Pearson I").

The Court of Appeals in Pearson I strongly suggested, without explicitly holding, that Plaintiffs' Antioxidant Vitamin Claim was only "potentially misleading," not "inherently misleading," and therefore the FDA's refusal to authorize the Antioxidant Vitamin Claim (or to propose a disclaimer to accompany the Claim) violated the First Amendment. Specifically, while Pearson I recognized the FDA's concern that the antioxidant health claim lacked "significant scientific agreement because existing research had examined only the relationship between consumption of foods containing these components and the risk of these diseases," the Court stated that the FDA's concern "could be accommodated...by adding a prominent disclaimer to the label." Id., 164 F.3d at 658 (emphasis in original).

Pearson I left the task of drafting precise disclaimers to the agency and acknowledged that in some circumstances a complete ban of a claim might be appropriate. Id., 164 F.3d at 659. While

recognizing the possibility that a disclaimer could be an inadequate guard against deceptiveness, the Court was "skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones [suggested by the Court] would bewilder consumers and fail to correct for deceptiveness." Id., 164 F.3d at 659-60.

In addition, Pearson I held that the FDA acted arbitrarily and capriciously in violation of the APA by failing to adequately define the "significant scientific agreement" standard for reviewing health claims that it had adopted pursuant to 21 U.S.C. § 343(r)(5)(D). Id., 164 F.3d at 660-61. Accordingly, the Court of Appeals directed the FDA on remand: (1) to determine whether a disclaimer could be added to the Antioxidant Vitamin Claim and other health claims to cure them of potentially misleading connotations, and (2) to explain "what it means by significant scientific agreement or, at minimum, what it does not mean." Id., 164 F.3d at 655, 660.

2. Remand to the FDA

As directed by the Court of Appeals, this Court remanded the case to the FDA on April 20, 1999. In response to the first order in Pearson I, the FDA published a notice requesting that interested parties submit scientific data concerning the four substance-disease relationships at issue in Pearson I, including the

antioxidant vitamin/cancer relationship.[7] 64 Fed. Reg. 48841 (Sept. 8, 1999); E.R. Tab 8. The FDA also contracted with a non-government entity "to conduct a literature search to identify for each of the four claims relevant scientific information that became available after the agency's initial review of these claims." Govt's Mem. in Opp'n to Pls.' Mot. for a Prelim. Inj. ("Govt's Opp'n") at 4-5. As a result of these two information-gathering measures, the FDA received a large number of post-1992 scientific studies describing the relationship between antioxidant vitamins and cancer that had been published since its 1993 rulemaking. Govt's Opp'n at 5. Among these were six submissions from Plaintiff that included 136 scientific references. Govt's Opp'n at 5.

In response to the second order in Pearson I that the FDA further define the "significant scientific agreement" standard for evaluating dietary supplement health claims, the FDA issued "Guidance for the Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" ("Guidance Report" or "Report") and announced its availability in the Federal Register. 64 Fed. Reg. 71794 (Dec. 22,

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[7] The comment period was originally scheduled to close on November 22, 1999. Upon Plaintiffs' request, the period was re-opened until April 3, 2000. The FDA also held a public meeting on April 4, 2000, for the purpose of soliciting comments relating to the implementation of the Court of Appeals Opinion. The comment period for this meeting closed on April 19, 2000.

1999), stating that the Report was available at http://www.cfsan.fda.gov/~dms/ssaguide.html ; E.R. Tab 12. The Guidance Report stated that significant scientific agreement meant that "the validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined." Id. at 2; E.R. Tab 12. The FDA further explained that

> Although significant scientific agreement is not consensus in the sense of unanimity, it represents considerably more than an initial body of emerging evidence. Because each situation may differ with the nature of the claimed substance/disease relationship, it is necessary to consider both the extent of agreement and the nature of the disagreement on a case-by-case basis.

Id. at 16-17; E.R. Tab 12.

In the Guidance Report, the agency also outlined the various aspects of its assessment of proposed health claims. For example, the FDA divided its analysis of studies on humans into interventional and observational studies and noted that "[i]n general, interventional studies provide the strongest evidence for [a supplement's] effect." Id. at 5; E.R. Tab 12. However, the agency stated that "[b]ecause of the limitations of various research methods that can be used to study substance/disease relationships" it would not be able to "specify the type or number of studies needed to support a health claim." Id. at 5; E.R. Tab 12.

On October 3, 2000, over 18 months after the Pearson I decision, the FDA published a notice revoking the four rules held unconstitutional by the Court of Appeals. 65 Fed. Reg. 58917, 58918 (Oct. 3, 2000).[8] However, the FDA continued to refuse to authorize the health claims at issue in Pearson I, including Plaintiffs' Antioxidant Vitamin Claim.

3. The Folic Acid/Neural Tube Defects Health Claim

On November 13, 2000, the Pearson Plaintiffs filed a lawsuit in this Court challenging the FDA's decision to prohibit inclusion of the folic acid/neural tube defect health claim at issue in Pearson I on dietary supplement labels. The folic acid/neural tube defects health claim was denied because the FDA thought the claim was inherently misleading even with clarifying disclaimers. See Pearson v. Shalala, 130 F.Supp.2d 105, 111-12 (D.D.C. 2001) ("Pearson II"). The Court found that the FDA had failed to comply with Pearson I and granted the Pearson Plaintiffs' request for a

[8] On March 31, 2000, the Pearson Plaintiffs filed an application for a preliminary injunction before this Court, contending that the FDA's continuing refusal to authorize Plaintiffs' Antioxidant Vitamin Claim and the three other claims, with or without disclaimers, violated the First Amendment under the Court of Appeals' ruling in Pearson I. On May 23, 2000, the Court denied the Pearson Plaintiffs' application, declaring, among other things, that "[b]ecause the FDA has not yet exhausted the 540-day period within which they must make a final decision on Plaintiffs' health claims, . . . Plaintiffs have not suffered any First Amendment injury which this Court can address." Pearson v. Shalala, Civ. A. No. 95-1865, 2000 WL 767584, at *3 (D.D.C. May 24, 2000) (Kessler, J.).

preliminary injunction, remanding the case to the FDA with instructions to draft one or more accurate disclaimers.

The Court found that "the FDA simply failed to comply with the constitutional guidelines" of Pearson I and stated that "the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion." Pearson II, 130 F.Supp.2d at 112. The Court concluded that the "FDA acted unconstitutionally, and particularly in violation of [Pearson I], in suppressing Plaintiffs' Claim rather than proposing a clarifying disclaimer to accompany the Claim." Id. at 120.

The FDA then moved for reconsideration of the Pearson II decision, claiming that the decision improperly considered relevant scientific evidence and created a legal standard inconsistent with Pearson I. In denying the motion, this Court noted that:

> Defendants again seem to ignore the thrust of Pearson I. While that decision might leave certain specific issues to be fleshed out in the course of future litigation, the philosophy underlying Pearson I is perfectly clear: that [] First Amendment analysis applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression.

Pearson v. Thompson, 141 F.Supp.2d 105, 112 (D.D.C. 2001) (Pearson III). The Court clarified the import of the previous Pearson decisions on the FDA's decision to suppress health claims by stating that both Pearson I and Pearson II "established a very

heavy burden which [Defendants] must satisfy if they wish to totally suppress a particular health claim." Pearson III, 141 F.Supp.2d at 112. Accordingly, the Court indicated that the FDA "must 'demonstrate with empirical evidence that disclaimers similar to [those] suggested...would bewilder consumers and fail to correct for deceptiveness.'" Id. (emphasis added) (citing Pearson I, 164 F.3d at 659-60). Accordingly, on June 4, 2001, the case was dismissed after an agreement was reached that allowed the labels of dietary supplements containing folic acid to display the folic acid/neural tube defect health claim with a disclaimer proposed by the FDA and chosen by the Pearson Plaintiffs.

4. Final FDA Action on the Antioxidant Vitamin Claim

On May 4, 2001, the FDA issued a letter decision in which it declared that it would not authorize Plaintiffs' Antioxidant Vitamin Claim given the agency's review of new antioxidant vitamin/cancer relationship studies under the "significant scientific agreement" standard described in the Guidance Report. Antioxidant Vitamin Decision, E.R. Tab 1A. The FDA found a lack of significant scientific agreement as to the relationship between antioxidant vitamin intake and reduction in the risk of developing cancer. Antioxidant Vitamin Decision at 77, E.R. Tab 1A. The FDA also found that the weight of the scientific evidence against the relationship was greater than the weight of evidence in favor of

the relationship, and therefore concluded that Plaintiffs' Antioxidant Vitamin Claim was "inherently misleading and cannot be made non-misleading with a disclaimer or other qualifying language." Id.

On July 17, 2001, Plaintiffs filed the present lawsuit.

III. Analysis

Plaintiffs contend that the FDA's Antioxidant Vitamin Decision fundamentally misread and misapplied the legal standard articulated by the Court of Appeals in Pearson I, in violation of the First Amendment. Plaintiffs further contend that the FDA's continued refusal to authorize the Antioxidant Vitamin Claim, even with disclaimers, causes them irreparable harm, thus necessitating the issuance of a preliminary injunction. Defendants respond that denial of the Antioxidant Vitamin Claim was based on the agency's conclusion that the scientific evidence weighed more heavily against than in favor of the antioxidant vitamin/cancer relationship, and therefore Plaintiffs' proposed health claim was misleading and incurable by disclaimer. The FDA contends that the Antioxidant Vitamin Claim is not protected speech because it is misleading and that the agency's decision to prohibit Plaintiffs' health claim was neither arbitrary nor capricious under the APA.

To obtain a preliminary injunction, Plaintiffs must show (1) a substantial likelihood of success on the merits; (2) a

substantial threat that they will suffer irreparable injury if the injunction is not granted; (3) that the threatened irreparable injury outweighs the threatened harm that the injunction would cause Defendants and third parties; and (4) that granting the preliminary injunction would be in the public interest. See Mova Pharm. Corp v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998); Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977).

Applying these four criteria, the Court concludes that a preliminary injunction is warranted in this case. Upon reviewing the FDA's Antioxidant Vitamin Decision conclusion that the Claim is "misleading and incurable by a disclaimer," the Court concludes that the FDA has failed to comply with the Court of Appeals decision in Pearson I and that Plaintiffs have demonstrated a substantial likelihood of success on the merits of their First Amendment claim.

The Court finds, as a matter of law, that Plaintiffs' Antioxidant Vitamin Claim is not "inherently misleading," and that the FDA therefore erred in not considering disclaimers to accompany the Claim. The FDA has failed to carry its burden of showing that suppression of Plaintiffs' Antioxidant Vitamin Claim is the least restrictive means of protecting consumers against the potential of being mislead by the Claim. As explained below, it is clear that

the FDA has once again failed to comply with the constitutional guidelines outlined in Pearson I.

However, as it is not the Court's institutional role to draft accurate, adequate, and succinct health claim disclaimers, see Pearson I, 164 F.3d at 659, the Court will require the FDA to draft and submit one or more alternative disclaimers, one of which may be selected by designers, sellers, and manufacturers of dietary supplements containing antioxidant vitamins. Because the Court is granting only limited relief to Plaintiffs at this time, see Order, Plaintiffs will not be authorized to design, sell, or manufacture their dietary supplements without an approved disclaimer.[9]

A. Plaintiffs Have Demonstrated a Substantial Likelihood of Success on the Merits.

The parties agree that the Antioxidant Vitamin Claim is commercial speech and that FDA's refusal to authorize Plaintiffs' proposed claim must, therefore, be evaluated under the analytical framework established in Central Hudson Gas & Elec. Corp. v. Public

[9] Plaintiffs request issuance of "an immediate preliminary injunction barring the FDA from taking any action to prohibit them from including on the labels and in the labeling of their dietary supplements that contain antioxidant vitamins [the Antioxidant Vitamin Claim]." Pls.' Application for Prelim. Inj. ("P.I. Mot.") at 34. Plaintiffs indicate that they are "willing to accept any reasonable short, succinct, and accurate disclaimer to guard against potential misleadingness." Id. Because the Court finds the Antioxidant Vitamin Claim to be "potentially misleading," the FDA must be given the opportunity, "in the first instance," to draft a clarifying disclaimer. Pearson I, 164 F.3d at 659.

Serv. Comm'n of New York, 447 U.S. 557 (1980), discussed extensively by our Court of Appeals in Pearson I, and elaborated on and reaffirmed by the Supreme Court in Thompson v. Western States Med. Ctr., __ U.S. __, 122 S.Ct. 1497 (2002).

Central Hudson directs the reviewing court to conduct a four-step analysis of speech regulation. First, the court must determine whether "the speech concerns lawful activity and is not misleading," Western States, 122 S.Ct at 1504, because a complete ban on commercial speech can only be approved where the government proves that "the expression itself was flawed in some way, either because it was deceptive or related to unlawful activity." Central Hudson, 477 U.S. at 566 n.9. Second, if the speech is protected, the court must determine "whether the asserted government interest is substantial." Western States, 122 S.Ct at 1504 (citing Central Hudson, 447 U.S. at 566). If the government interest is substantial, the court must then determine "whether the regulation directly advances the governmental interest asserted." Pearson I, 164 F.3d at 657 (emphasis in original) (citing Central Hudson, 447 U.S. at 566). Finally, the court must determine "whether [the regulation] is not more extensive than is necessary to serve that interest." Western States, 122 S.Ct at 1504 (citing Central Hudson, 447 U.S. at 566). This fourth step requires an evaluation of "whether the fit between the government's ends and the means

chosen to accomplish those ends is . . . reasonable." Pearson I, 164 F.3d at 656 (internal citations and quotations omitted).

In examining restrictions on commercial speech under the First Amendment, the Supreme Court has consistently "rejected the 'highly paternalistic' view that government has complete power to suppress or regulate commercial speech" in order to protect the public. Central Hudson, 447 U.S. at 562. Thus, in finding that speech is misleading, the government must consider that "people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them." Virginia Pharmacy Board v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976).

The First Amendment places the burden on the government to prove that its method of regulating speech is the least restrictive means of achieving its goals. See Western States, 122 S. Ct. at 1506 (Under the Central Hudson analysis, it is "clear that if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so."); Pearson I, 164 F.3d at 659 (The government "must still meet its burden of justifying a restriction on speech."). The First Amendment does not allow the FDA to simply assert that Plaintiff's Claim is misleading in order to "supplant [its] burden to demonstrate that the harms it recites are real and that its

restriction will in fact alleviate them to a material degree." Ibanez v. Florida Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146 (1994) (internal citations omitted). In this case, the Government has not satisfied its burden--there is no evidence that the proposed Antioxidant Vitamin Claim, if accompanied by a disclaimer, would be deceptive or unlawful.

1. Plaintiffs' Antioxidant Vitamin Claim Is Not Inherently Misleading Commercial Speech.

Turning to the first step of the Central Hudson analysis, we begin with the Court of Appeals' strong suggestion in Pearson I that Plaintiffs' Antioxidant Vitamin Claim was only potentially misleading, not inherently misleading. While the Supreme Court has held that "inherently" misleading information may be banned in its entirety, it has also reasoned that so long as information can be presented in a way that is not deceptive, such information is only potentially misleading--not inherently misleading. In re R.M.J., 455 U.S. 191, 203 (1982). As such, the government "may not place an absolute prohibition on certain types of potentially misleading information," id., because even when speech "communicates only an incomplete version of the relevant facts,...some accurate information is better than no information at all." Central Hudson, 447 U.S. at 562 (internal citations omitted) (emphasis added). For this reason, the Court of Appeals concluded that addition of a

clarifying disclaimer to a potentially misleading health claim would provide the public with information while satisfying the government's concerns about the completeness of the information being provided. Pearson I, 164 F.3d at 659.

Based upon its review of the most recent scientific evidence,[10] the FDA determined that Plaintiffs' Antioxidant Vitamin Claim is "inherently misleading and cannot be made non-misleading with a disclaimer." Antioxidant Vitamin Decision at 77, E.R. Tab 1A. Given the FDA's continual refusal to authorize the disclaimers suggested by the Court of Appeals, or any other disclaimers, as well as the FDA's resistance to the teachings of Pearson I, it is essential to carefully review the analysis it relied upon to ban Plaintiffs' Antioxidant Vitamin Claim in the context of the Pearson I opinion.

a. Pearson I clearly considered the circumstances in which the FDA might ban a claim as misleading based on scientific evidence.

The Court of Appeals established clear guidelines for the FDA in determining whether a particular health claim may be deemed "inherently misleading" and thus subject to total suppression. The Court implied, though it did not declare explicitly, that when

[10] Because studies of the relationship between antioxidant vitamin supplements were limited in 1993, the FDA's initial review of the Antioxidant Vitamin Claim focused on the relationship between foods containing vitamins C and E and the risk of cancer. Pearson I, 164 F.3d at 658.

"credible evidence" supports a claim, that claim may not be absolutely prohibited. Pearson I, 164 F.3d at 659. While the Court did not "rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright," it is clear that the Court was alluding to a very narrow set of circumstances in which suppression would be permissible under the First Amendment. Id.

Specifically, Pearson I identified two situations in which a complete ban would be reasonable. First, when the "FDA has determined that no evidence supports [a health] claim," it may ban the claim completely. Id., 164 F.3d at 659-660 (emphasis in original). Second, when the FDA determines that "evidence in support of the claim is qualitatively weaker than evidence against the claim--for example, where the claim rests on only one or two old studies," it may impose an outright ban. Id., 164 F.3d at 659 n.10 (emphasis added). Even in these two situations, a complete ban would only be appropriate when

> the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above ["The evidence in support of this claim is inconclusive" or "The FDA does not approve this claim"] would bewilder consumers and fail to correct for deceptiveness.

Id., 164 F.3d at 659-660 (emphasis added). Moreover upon reviewing

the four claims prohibited by the FDA, including the Antioxidant Vitamin Claim, the Court indicated that it was "skeptical" that the government would be able to provide such evidence. Id.

Thus, two conclusions emerge from a close reading of Pearson I. First, the Court of Appeals did not rule out the possibility that disclaimers would not be able to correct the inherent misleadingness of some health claims. Second, the Court stated that any complete ban of a claim would be approved only under narrow circumstances, i.e., when there was almost no qualitative evidence in support of the claim and where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer.

b. FDA review of the Antioxidant Vitamin Claim did not conform with its own Guidance Report.

While the Court is mindful that it is generally "not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence," NRDC v. EPA, 824 F.2d 1211, 1216 (D.C. Cir. 1987), our Court of Appeals has also cautioned that the courts "must ensure that the [agency] has examined the relevant data and articulated an adequate explanation for its action." International Fabricare Institute v. E.P.A., 972 F.2d 384, 389 (D.C. Cir. 1992). The deference due to an agency's expert evaluation of scientific data does not negate "the duty of [the] court to ensure that an

agency...conduct a process of reasoned decisionmaking." K N Energy, Inc. v. F.E.R.C., 968 F.2d 1295, 1303 (D.C. Cir. 1992) (emphasis in original).

Similarly, a court must also examine an agency's reasoning to determine whether its decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" under the APA, 5 U.S.C. § 706(2)(A). An agency's decision may be overturned under the APA when it "has failed to respond to specific challenges that are sufficiently central to its decision." International Fabricare Institute, 972 F.2d at 389. The significant constitutional concerns in this case further underscore this Court's "duty of holding agencies to certain minimal standards of rationality." Ethyl Corp. v. E.P.A., 541 F.2d 1, 36 (D.C. Cir. 1976).

In reaching its May 4, 2001, antioxidant vitamin decision, the FDA reviewed more than 150 studies examining the relationship between antioxidant vitamins and various types of cancer and reached two conclusions.[11] First, it decided that there was not significant scientific agreement that the available evidence supported the antioxidant vitamin/cancer relationship. Antioxidant

[11] The FDA considered intake of vitamins C and E with relation to risk of developing bladder, breast, cervical, colorectal, lung, oral/pharyngeal/esophageal, pancreatic, prostate, skin, and stomach cancers.

Vitamin Decision at 3-4, E.R. Tab 1A. Second, the FDA concluded that the scientific evidence against the Antioxidant Vitamin Claim outweighed the evidence for the claim because the studies that suggested support for the claim were "[in]sufficient, on balance, to support a qualified claim...in such a way as not to mislead consumers." Antioxidant Vitamin Decision at 76, E.R. Tab 1A. Consequently, the FDA rejected the Plaintiffs' health claim as misleading and not curable by disclaimer.

Turning to a review of the record upon which the FDA relied, we see that approximately one-third of the more than 150 intervention and observational studies considered by the FDA support the antioxidant vitamin/cancer relationship.[12] In reviewing

[12] Of the antioxidant vitamin/cancer studies reviewed by the FDA:

a) Five of seventeen intervention studies supported the relationship, and one study produced mixed reports both for and against the relationship;

b) Two of six post-hoc intervention studies supported the relationship; and

c) Sixty-five of 191 observational studies supported the relationship as did the one observational meta-analysis reviewed by the FDA.

However, the FDA discounted many of the studies supporting the relationship for study errors or design limitations. See, e.g., Antioxidant Vitamin Decision at 20 (A meta-analysis study supporting a vitamin c - breast cancer relationship "must be viewed with caution."); 27 (Studies supporting a vitamin c-cervical cancer relationship were given "very little weight in its analysis."); and 71 (Support for a vitamin E-stomach cancer relationship was interpreted with caution.)

these studies, the FDA said it gave appropriate weight to the findings based on the protocol established in the Guidance Report. See Antioxidant Vitamin Decision at 9-15, E.R. Tab 1A. That Report states that intervention studies should be weighed more heavily than observational studies. Thus, the FDA simply failed to follow its own Report and give appropriate weight to the approximately one-third of the intervention studies that supported the Plaintiffs' Claim.

The FDA also stated that it banned the Plaintiffs' Claim based on the lack of evidence that consumption of antioxidant vitamin supplements reduced cancer risk in the general population. Antioxidant Vitamin Decision at 3-4, E.R. Tab 1A (emphasis added). However, contrary to its own protocols, the FDA gave undue emphasis to many intervention studies that did not focus on the general population, but rather focused on specific populations that were at a higher risk for cancer (i.e., smokers at risk for lung cancer). While the FDA admits that some heavily-weighted studies involved populations with "higher than normal cancer rates" or with "non-cancerous lesions from which cancer develops," it argues that a lack of support for the antioxidant vitamin/cancer relationship in these populations would indicate that it was "unlikely that there would be an effect in the generally healthy population as well." Gov't Opp'n at 21, 22.

It is difficult to discern the logic in this argument--the fact that a high risk population would not be helped by antioxidant vitamins hardly proves that a low risk population would not be benefitted. Quite the contrary, it may well be that a low-risk population would be benefitted by a vitamin supplement that failed to help a population with increased vulnerability to disease.[13]

The FDA's emphasis on studies involving pre-cancerous populations runs directly contrary to the protocol established in its Guidance Report. The Report clearly states that "[a]lthough interventional studies are the most reliable category of studies for determining cause-and-effect relationships, generalizing from selected populations often presents serious problems in the interpretation of such studies." Guidance Report at 6; E.R. Tab 12. Yet, that is precisely what the FDA did when it generalized from studies of high-risk populations to evaluate the Plaintiffs' health claim.

[13] In fact, the FDA took a markedly different position when questioning the results of certain studies that indicated support for the Plaintiffs' Antioxidant Vitamin Claim but had been based on populations which were unlike the general, U.S. population. See, e.g., Antioxidant Vitamin Decision at 67 (The FDA found the relevance of one vitamin C-stomach cancer study "unclear due to the fact that the trial was conducted in a population … with a very high incidence of stomach cancer."), and 68 (Results of a study supporting the vitamin C-stomach cancer relationship were unclear given the "nutritional differences between this poorly nourished Chinese population and the U.S. population.").

The Report also supports Plaintiffs' argument that more weight should be given to studies of the general population. Significantly, the FDA explained that assessing the quality of substance/disease relationships would in part depend on whether the study population was representative of the population to which the health claim will be targeted for factors such as health status. Guidance Report at 12; E.R. Tab 12. Once again, the FDA's choice to rely more heavily on studies of high-risk populations than on studies representative of the population to which the Plaintiffs' claim is targeted, did not adhere to the teachings of its own Guidance Report.

In short, the basic finding upon which the FDA rests its decision to ban the Plaintiffs' claim, i.e., that the claim is misleading because the evidence against it outweighs the evidence in support of it, is unreasonable because it is not supported by an overall review of the available evidence or the FDA's own Guidance Report.

c. The circumstances under which the FDA might ban a claim as misleading based on scientific evidence are not present in this case.

Even if the FDA's analysis of the Antioxidant Vitamin Claim were reasonable, the government must satisfy a heavy burden to prove that suppression of commercial speech is allowed under the

First Amendment.[14] After carefully reviewing the FDA's Guidance Report, the evidence upon which the FDA relied, and the FDA's conclusion that the evidence against the Plaintiffs' claim clearly outweighs the evidence in support of it, the Court finds that the FDA's decision to ban the claim completely is not in accordance with the law as set forth by the Court of Appeals in Pearson I.

First, while the Court of Appeals stated that a complete ban would be reasonable where there was no evidence to support a claim, Pearson I, 164 F.3d at 659-660 (emphasis in original), that is not the case here. It is undisputed that the FDA identified some evidence (approximately one-third of the total evidence examined) in support of the Antioxidant Vitamin Claim. Therefore, a complete ban of the Claim cannot be justified.

Second, the Court of Appeals stated that a claim might be banned if there was qualitatively weak supporting evidence found in "only one or two old studies." Pearson I, 164 F.3d at 659 n.10. The FDA has banned the Plaintiffs' claim by concluding that the evidence in support of it was weaker than evidence against it, but it is clear that more than 60 recent studies reviewed by the FDA

[14] Plaintiffs also claim that "health agencies of the federal government other than the FDA have published that antioxidant vitamins may reduce the risk of certain kinds of cancer." Pl's Mem. in Support of Pls.' Mot. for a Prelim. Inj. at 15-16. However, upon de novo constitutional review of the exhibits, the Court agrees with the Government that the claim is inaccurate. Govt's Opp'n at 22-23.

supported the claim. This hardly constitutes the "one or two old studies" that the Court of Appeals contemplated might support a total ban.

Third, even if the FDA's decision to ban the Claim could be justified by finding that the evidence in support of it was clearly qualitatively weaker than the evidence against it, the FDA has failed to provide empirical evidence that an appropriate disclaimer would confuse consumers and fail to correct for deceptiveness. Pearson I, 164 F.3d at 659-660. Again, the FDA's decision to ban Plaintiffs' claim is not in accordance with Pearson I.

As noted earlier, even though Pearson I recognized the possibility that the deceptiveness of some health claims might not be curable by disclaimers, the complete ban of a claim would be approved only under narrow circumstances--where there was little-to-no scientific evidence in support of the claim and where the government could prove that the public would still be deceived by the claim even with the use of accompanying disclaimers. Consequently, the Court conlcudes that the FDA's rejection of Plaintiffs' claim has failed to satisfy both the Pearson I conditions for a total ban--becauseone-third of the studies that the FDA reviewed supported the Antioxidant Vitamin Claim and the FDA failed to provide empirical evidence that consumers would be deceived by the use of the claim if accompanied by a disclaimer.

2. Considering the Antioxidant Vitamin Claim in Totality, the FDA Has Failed to Follow the First Amendment Analysis Mandated by Central Hudson, Pearson I and Western States.

As the overall evidence considered by the FDA weighs on both sides of the antioxidant vitamin/cancer relationship, the rare circumstances identified in Pearson I authorizing a complete ban based on a claim's inherent misleadingness are not present. Accordingly, at the first stage of the Central Hudson analysis, the Court determines, as a matter of law, that the Antioxidant Vitamin Claim is only potentially misleading, not inherently misleading, because the information might be presented in way that is not deceptive--with a clarifying disclaimer as suggested by the Court of Appeals. Pearson I, 164 F.3d at 659.

Having considered the very Antioxidant Vitamin Claim which is at issue in this case, the Court of Appeals found the FDA's substantial interest in "protection of public health and prevention of consumer fraud" was "undeniable" under Central Hudson's second step. Pearson I, 164 F.3d at 655-56. The third step of Central Hudson was also satisfied because the FDA's regulation of dietary supplement health claims directly advances its interest in "protecting against consumer fraud." Pearson I, 164 F.3d at 656. The Court of Appeals reasoned that the regulations would prevent

confusion by ensuring that consumers had non-misleading information about the health products they contemplated purchasing. Id.

As the FDA has satisfied the second and third steps of the Central Hudson test in the present case,[15] the key analysis comes under Central Hudson's final step--whether there is a reasonable fit between the government's goals and the means it has chosen to achieve them. In determining whether there is a reasonable fit between the FDA's goals of consumer protection and its decision to ban Plaintiffs' Antioxidant Vitamin Claim, the Supreme Court has clearly stated that "if the Government could achieve its interests in a matter that does not restrict speech, or that restricts less speech, the Government must do so." Western States, 122 S.Ct. at 1506 (emphasis added). In its review of the relevant Supreme Court decisions, our Court of Appeals also concluded--even before issuance of Western States--that disclaimers were "constitutionally preferable to outright suppression." Pearson I, 164 F.3d at 657 (internal citations omitted). In other words, more disclosure rather than less is the preferred approach, so long as commercial

[15] Plaintiffs also contend that the FDA is suppressing their claim in order to protect the new drug approval process. While the FDA does not articulate such an interest, the Supreme Court recently rejected the FDA's practice of suppressing speech to protect an asserted interest in protecting new drug approval process. Western States, 122 S.Ct. at 1504-06.

speech is not inherently misleading. Pearson I, 164 F.3d at 657 (citing Bates v. State Bar of Arizona, 433 U.S. 350, 376 (1977)).

Given that the First Amendment "means that regulating speech must be a last–-not first--resort," the burden in this case is on the FDA to prove that suppression of the Antioxidant Vitamin Claim "was a necessary as opposed to merely convenient means of achieving its interests." Western States, 122 S.Ct. at 1507 (emphasis added).[16] The Court of Appeals' earlier review of the FDA's denial of the Plaintiffs' Antioxidant Vitamin Claim found that the FDA's justifications for suppression were merely "conclusory assertions [that fell] far short" of satisfying its burden and concluded that the FDA had not chosen a less restrictive means of protecting its interests, i.e., a disclaimer. Pearson I, 164 F.3d at 659.

Once again in its 2001 decision, the FDA has failed to recognize that its decision to suppress the Plaintiff's Antioxidant Vitamin Claim does not comport with the First Amendment's clear preference for disclosure over suppression of commercial speech.

B. Plaintiffs Will Suffer Irreparable Harm by the Refusal of FDA to Allow a Qualified Antioxidant Vitamin Claim.

The case law makes it very clear that Plaintiffs are harmed by the FDA's suppression of the Antioxidant Vitamin Claim because the

[16] Congress considered it important that health claims be presented to the public to enable them to make an informed decision regarding "the relative significance of the [health] claim in the context of [their] total daily diet." H.R. Rep. 101-538, at 21 (1990).

"loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion) (citing New York Times Co. v. United States, 403 U.S. 713 (1971)); see also Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 758 (1988) (noting that "opportunities for speech," if suppressed, "are irretrievably lost"). Accord, National Treasury Employees Union v. United States, 927 F.2d 1253, 1254 (D.C. Cir. 1991), Wagner v. Taylor, 836 F.2d 566, 576 n.76 (D.C. Cir. 1987).[17]

Given that Plaintiffs have suffered a loss of their First Amendment freedoms for more than a minimal period of time because nine years have passed since the FDA first prohibited the Antioxidant Vitamin Claim in 1993, the FDA's unconstitutional suppression of Plaintiffs' claim clearly constitutes irreparable harm.

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[17] Defendants imply that Elrod and its progeny do not apply to commercial speech because the case law indicates "that commercial speech, unlike political speech, is more durable and not easily chilled." Govt's Opp'n at 40. However, while the Supreme Court cases that the Government cited in support of its argument noted that commercial speech was different from other types of speech, the Supreme Court still concluded in each of those cases that the First Amendment allows only limited regulation of commercial speech. See Virginia State Board of Pharmacy; Central Hudson; and Friedman v. Rogers, 440 U.S. 1 (1979).

C. Potential Harm to the Public Does Not Outweigh Plaintiffs' First Amendment Injury.

Defendants contend that the Antioxidant Vitamin Claim will mislead and harm third parties (namely, consumers) and therefore is not beneficial to the public. The Court is well aware of the vital role the FDA plays in protecting vulnerable consumers from fraud in the labeling and marketing of foods and dietary supplements. However, under the governing analysis set forth in Western States and Pearson I, even if Plaintiffs' Antioxidant Vitamin Claim is in some respects "potentially" misleading, the resulting injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury Plaintiffs have continually borne in the more than three years since Pearson I was decided.

It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited. Significantly, the FDA has not relied on any argument that consumption of antioxidant supplements will cause any physical or medical harm to the public.[18] At worst, any deception resulting

[18] Because the FDA chose not to exercise its enforcement discretion to allow a qualified disclaimer, the agency found it unnecessary to evaluate the potential safety concerns about ingestion of antioxidant vitamins at very high levels. However, there is ample evidence that the dosages contained in Plaintiffs' antioxidant supplements are safe. See Pl's Exhibit 25, Food and Nutrition Board, Institutes for Medicine, Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids 162, 258 (2000) (Vitamins C and E are safe for human consumption by the general populations up to the daily limits of 2,000 mg of Vitamin C and

(continued...)

from Plaintiffs' health claim will result in consumers spending money on a product that they might not otherwise have purchased. This type of injury, while obviously not insignificant, cannot compare to the harm resulting from the unlawful suppression of speech.

D. The Public Interest Would Be Served by FDA's Approval of an Antioxidant Vitamin Claim.

The issuance of an injunction in support of Plaintiffs' Antioxidant Vitamin Claim would serve the public interest in three ways. First, it is clearly in the public interest to ensure that governmental agencies, such as the FDA, fully comply with the law, especially when we are concerned with the parameters of a First Amendment right to effectively communicate health messages to consumers. Second, Congress enacted NLEA with the intention that consumers would have access to the information in health claims in order to make informed dietary decisions. H.R. Rep. 101-538, at 21 (1990). Third, the public health risk from cancer is undeniably substantial. See American Cancer Society, Cancer Facts & Figures 2002 at 1-3. (2002) (Cancer is the second leading cause of death in the United States; more than 16 million new cancer cases have

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(...continued)
1,000 mg of Vitamin E and pose no carcinogenic or other risk of injury/illness at those levels.); Pl's Exhibit 3, National Institutes of Health, Facts About Dietary Supplements: Vitamin E (Aug. 7, 2001), available at http://www.cc.nih.gov/ccc/supplements/vite.html (The health risk of too much Vitamin E is low.).

been diagnosed since 1990; and the government estimates that overall costs for cancer in 2001 exceeded $150 billion.). The types of cancers for which the FDA reviewed the Antioxidant Vitamin Claim occur throughout the U.S. population. Given that one-third of the scientific studies reviewed by the FDA found that consumption of antioxidant vitamins reduced adults' risk of developing certain types of cancer, the public interest is well served by permitting information about the antioxidant vitamin/cancer connection to reach as wide a public audience as possible. Plaintiffs' Antioxidant Vitamin Claim, with appropriate disclaimers, communicates an important message that the American public is entitled to hear and evaluate.

IV. Conclusion

For the reasons stated, the Court finds that the FDA's decision to completely prohibit Plaintiffs' Antioxidant Vitamin Claim as "inherently misleading" was unconstitutional and "not in accordance with law" under the APA, 5 U.S.C. § 706(2)(A). Plaintiffs' proposed Claim is only potentially misleading and therefore subject to First Amendment protection. Accordingly, the Court concludes that the FDA has acted in violation of the Court of Appeals decision in Pearson I by suppressing Plaintiffs' Claim rather than proposing a clarifying disclaimer to accompany the Claim. Accordingly, the Court **grants** Plaintiffs' Motion for a

Preliminary Injunction insofar as it requests a declaration that the FDA's refusal to authorize the Antioxidant Vitamin Claim violates the First Amendment.[19]

However, because it is the FDA's, rather than the Court's, institutional role to draft accurate, adequate, and succinct health claim disclaimers, the Court hereby **remands this case to the FDA**, instructing the agency to draft and submit one or more such appropriately short, succinct, and accurate disclaimers.[20] The Court strongly suggests that, at a minimum, the agency consider the two disclaimers suggested by the Court of Appeals in Pearson I ("The evidence in support of this claim is inconclusive" and "The FDA does not approve this claim").

An Order will issue with this Opinion.

_____ _____

Date Gladys Kessler
United States District Judge

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[19] See supra note 10.

[20] The Court is aware that there are certain constraints on its ability to mandate specific time limits for agency action. See Consumer Fed'n of Am. and Pub. Citizen v. United States Dep't of Health and Human Servs., 83 F.3d 1497, 1506-07 (D.C. Cir. 1996). However, there is no question that the agency has acted with less than reasonable speed in this case, as demonstrated by its 18 month delay in revoking rules declared unconstitutional by the Court of Appeals in Pearson I. Consequently, the Court anticipates that the agency will complete its task within 60 days.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action
	)	No. 01-1539 (GK)
TOMMY G. THOMPSON, Secretary, Department of Health and Human Services, et al.,	)	
	)	
Defendants,	)	

O R D E R

This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction [#4]. For the reasons stated in the accompanying Memorandum Opinion, it is this _____ day of December, 2002,

ORDERED, that Plaintiffs' Motion for a Preliminary Injunction **[#4]** is **granted,** insofar as it requests a declaration that the Food and Drug Administration's May 4, 2001, denial of Plaintiffs' Antioxidant Vitamin Claim ("Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers.") violates the First Amendment of the U.S. Constitution; and it is further

ORDERED, that this case is **remanded**, effective immediately, to the Food and Drug Administration, for the purpose of drafting one or more short, succinct, and accurate alternative disclaimers,

which may be chosen by Plaintiffs to accompany their Antioxidant Vitamin Claim, consistent with the accompanying Memorandum Opinion.

_____
Gladys Kessler
United States District Judge

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